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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,438

01/29/2008

Monika Kroz

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2609

23307 7590 05/26/2009

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EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

05/26/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/584,438	KROZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DONG JIANG	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-24, 27 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25, 26, 28, 29 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/6/08 &amp; 10/16/08</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED OFFICE ACTION**

Applicant's election of Group III invention and the species election of minimizing a side effect associated with IL-11 treatment, filed on 05 March 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Currently, claims 1-33 are pending, and claims 25, 26, 28, 29 and 33 are under consideration. Claims 1-24, 27 and 30-32 are withdrawn from further consideration as being drawn to a non-elected invention.

#### **Formal Matters:**

##### ***Information Disclosure Statement***

Applicant's IDSs submitted on 10/16/08 and 11/6/08 are acknowledged and have been considered (note, they are identical). A signed copy is attached hereto.

##### ***Priority acknowledgement***

This application is a national stage entry (371) of PCT/GB2004/005091 with the international filing date of 12/3/04, which is acknowledged.

It is noted that this application also claims benefit to a foreign application (03027770.1). However, no certified copy of the foreign priority document is supplied or found in the record of the present application.

##### ***Drawings***

This application lacks formal drawings, for example, Figure 12. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

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***Specification******Title***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed (a method).

***Claims***

Applicant is advised that should claim 25 be found allowable, claim 33 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof; and that should claim 28 be found allowable, claim 29 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

**Rejections under 35 U.S.C. §112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 26, 28, 29 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is indefinite and confusing for the recitation “minimizing a side effect associated with the treatment ... with IL-11 comprising administering an albumin-fused IL-11” because it sounds like that the side effect is caused by IL-11, then, it is unclear how or why the side effect caused by IL-11 is treated by IL-11. Claim 33 is similarly indefinite.

Claim 26 is indefinite for the recitation “suffering from a bowel disorder and the side effect is weight loss, ...” because, again, it is unclear whether the bowel disorder is associated with IL-11 treatment or is the original disorder before IL-11 treatment; and whether weight loss, etc. is a part of the original disorder or is associated with IL-11 treatment. The metes and bounds of the claim, therefore, cannot be determined.

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Claim 28 is incomplete because it depends on non-elected claim 1. The claim is further indefinite for the recitation of “an effective amount” because it is unclear for what it is effective, and how the “effective amount” can be determined, as there is no specific disease or condition recited, which could be treated with the said composition, since the preamble merely recites “treating a disease or disorder”. The metes and bounds of the claim, therefore, cannot be determined. Claim 29 is similarly indefinite.

**Rejections Over Prior Art:**

Claim interpretation: As the claims are indefinite for the reasons above, it is not clear whether the claims are directed to a method for treating a side effect caused by IL-11 treatment with the albumin-fused IL-11, or a method for treating a disease/disorder such as a bowel disorder with the albumin-fused IL-11. In light of the specification disclosure (Example 7, for instance), the claims are interpreted as to a method for treating a disease/disorder such as a bowel disorder with the albumin-fused IL-11 (although it is generally considered improper to read limitations contained in the specification into the claims (see MPEP 2173.05 (q))).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 26, 28, 29 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosen et al., US2003/0219875 A1 (11/27/03).

Rosen discloses albumin fusion proteins as therapeutic proteins, and teaches that therapeutic proteins may be stabilized to extend the shelf-life, and/or retain the therapeutic protein's activity for extended periods of time in solution, in vitro and/or in vivo, by genetically or chemically fusing or conjugating the therapeutic protein to albumin, that is sufficient to stabilize the protein and/or its activity (abstract, and page 1, 2<sup>nd</sup> column, [0008]). Further, Rosen teaches that such therapeutic proteins (albumin fusion proteins) include, among others, IL-11, which is indicated for the treatment of diseases/conditions such as Crohn's disease (page 4, 2<sup>nd</sup> column, [0046], lines 1-3; and Table 1 on page 18). Note, Crohn's disease is a bowel disorder with weight loss, rectal bleeding and/or diarrhoea. As such, the reference anticipates the present claims.

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**Conclusion:**

No claim is allowed.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Examiner Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dong Jiang/  
Primary Examiner, Art Unit 1646  
5/22/09